Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 530

NORTON HEALTHCARE LIMITED 2: Name of authorisation holder

NORTON HEALTHCARE LIMITED T\A IVAX PHARMACEUTICALS UK, 3: Address(es) of manufacturing site(s)

ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE,

RUNCORN, WA7 3FA, UNITED KINGDOM

NORTON HEALTHCARE LIMITED, ACCOUNTS PAYABLE

4: Legally registered address of authorisation holder DEPARTMENT, RIDINGS POINT, WHISTLER DRIVE, CASTLEFORD

WF10 5HX, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 6: Legal Basis of authorisation

[SI 2004/1031]

7: Name of responsible officer of the competent

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 18/09/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

NORTON HEALTHCARE LIMITED T\A IVAX PHARMACEUTICALS UK, ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE, RUNCORN, WA7 3FA, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.1.1.6] Other aseptically prepared products

Suspensions and Emulsions

[1.1.3] Batch certification

Issue Date: 18 Sep 2025

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Monoclonal Antibodies

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Monoclonal Antibodies

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological



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